PATENT
P-2821RI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): James G. Nadeau et al.

REISSUE OF. Patent No. 5,547,861 GROUP: Not Assigned

FILING DATE: Herewith EXAMINER: Not Assigned

FOR: DETECTION OF NUCLEIC ACID AMPLIFICATION

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231

ON: May 20, 1998
(DATE OF DEPOSIT)

BY: Mary Lou Kittren
(NAME)

Mary Lou Kittren 5-20-98
(SIGNATURE) (DATE)

DECLARATION UNDER 37 C.F.R. §1.175 AND POWER OF ATTORNEY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

We, James G. Nadeau, a citizen of the United States and having a Post Office address of 710 Coker Lane, Chapel Hill, North Carolina 27514 and George T. Walker, a citizen of the United States and having a Post Office address of 209 Mt. Bolus Road, Chapel Hill, North Carolina 27514 hereby declare that:

We believe that we are the original, first and joint inventors of the invention described and claimed in the United States Letters Patent No. 5,547,861 and in the above-identified reissue application.

We have reviewed and understand the contents of the above-identified application. We acknowledge our duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

We believe the original patent grant U.S. Patent No. 5,547,861 is partially inoperative, through inadvertent error without any deceptive intent by reason of applicants claiming less than they had a right to claim in that applicants mistakenly limited all claims in U.S. Patent No. 5,547,861 to specify only methods for concurrently generating a secondary amplification product and an amplification product.

We further mistakenly limited all claims to specify one embodiment of a Strand Displacement, Amplification (SDA) reaction with its requisite components, namely (i) a DNA polymerase having strand displacing activity and lacking 5'-3' exonuclease activity and (ii) a restriction endonuclease which nicks a hemimodified double stranded restriction endonuclease recognition site. Specifically, we failed to include the following claims which, together with the claims originally issued for U.S. Patent No. 5,547,861, form the reissue claims of the above-referenced reissue application.

(1) A claim 21 reciting a method for concurrently generating a secondary amplification product and an amplification product in a nucleic acid amplification reaction, the method comprising:

a) hybridizing a signal primer to a target sequence and hybridizing a first amplification primer to the target sequence upstream of the signal primer;

b) extending the hybridized signal primer on the target sequence to produce a signal primer extension product and extending the hybridized first amplification primer on the target sequence such that extension of the first amplification primer displaces the signal primer extension product from the target sequence;

c) hybridizing a second amplification primer to the signal primer extension product and extending the hybridized second amplification primer on the signal primer extension product to produce a second amplification primer extension product comprising a newly synthesized strand;

d) displacing the newly synthesized strand from the signal primer extension product; and

e) hybridizing the signal primer to the displaced newly synthesized strand and extending the signal primer such that a double stranded secondary amplification product is generated;

(2) a claim 22, worded similarly to original patent claim 2, but dependent from claim 21;

(3) a claim 23, worded similarly to original patent claim 3, but dependent from claim 22;

(4) a claim 24, worded similarly to original patent claim 4, but dependent from claim 22;

(5) a claim 25, worded similarly to original patent claim 5, but dependent from claim 22;

(6) a claim 26, dependent from claim 25, reciting detection of the secondary amplification product by cleaving the restriction endonuclease recognition site with a restriction endonuclease to generate a cleavage product;

(7) a claim 27, dependent from claim 26, reciting detection of the secondary amplification product by separating the cleavage product on the basis of size and detecting the cleavage product;

(8) a claim 28, worded similarly to original patent claim 7, but dependent from claim 27;

(9) a claim 29 reciting a method for concurrently generating a secondary amplification product and an amplification product in a nucleic acid amplification reaction, the method comprising:

a) hybridizing a first signal primer to a first strand of a double-stranded target sequence and hybridizing a first amplification primer to the first strand of the target sequence upstream of the first signal primer;

b) extending the hybridized first signal primer on the first strand to produce a first extension product and extending the hybridized first amplification primer on the first strand such that extension of the first amplification primer displaces the first extension product from the target sequence;

c) hybridizing a second signal primer to the first extension product and hybridizing a second amplification primer to the first extension product upstream of the second signal primer;

d) extending the hybridized second signal primer on the first extension product to produce a second extension product and extending the hybridized second amplification primer on the first extension product such that extension of the second amplification primer displaces the second extension product from the first extension product; and

e) hybridizing the first signal primer to the displaced second extension product and extending the hybridized first signal primer on the second extension product such that a double stranded secondary amplification product is generated;

(10) a claim 30, worded similarly to original patent claim 9, but dependent from claim 29;

(11) a claim 31, dependent from claim 29, reciting the inclusion of further steps:

a) hybridizing the second signal primer to a second strand of the double stranded target sequence and hybridizing the second amplification primer to the second strand of the target sequence upstream of the second signal primer;

b) extending the hybridized second signal primer on the second strand to produce a third extension product and extending the hybridized second amplification primer on the second strand such that extension of the second amplification primer displaces the third extension product from the second strand of the target sequence;

c) hybridizing the first signal primer to the displaced third extension product and hybridizing the first amplification primer to the displaced third extension product upstream of the first signal primer;

d) extending the hybridized first signal primer on the third extension product to produce a fourth extension product and extending the hybridized first amplification primer on the third extension product such that extension of the first amplification primer displaces the fourth extension product from the third extension product; and

e) hybridizing the second signal primer to the displaced fourth extension product and extending the second signal primer on the fourth extension product such that a double stranded secondary amplification product is generated;

(12) a claim 32, worded similarly to original patent claim 11, but dependent from claim 31;

(13) a claim 33, worded similarly to original patent claim 12, but dependent from claim 32;

(14) a claim 34, worded similarly to original patent claim 13, but dependent from claim 32;

(15) a claim 35, worded similarly to original patent claim 14, but dependent from claim 32;

(16) a claim 36, dependent from claim 35, reciting detection of the secondary amplification product by cleaving the restriction endonuclease recognition site with a restriction endonuclease to generate a cleavage product;

(17) a claim 37, dependent from claim 36, reciting detection of the secondary amplification product by separating the cleavage product on the basis of size and detecting the cleavage product;

(18) a claim 38, worded similarly to original patent claim 16, but dependent from claim 37;

(19) a claim 39, worded similarly to original patent claim 17, but dependent from claim 22;

(20) a claim 40, worded similarly to original patent claim 18, but dependent from claim 22;

(21) a claim 41, worded similarly to original patent claim 19, but dependent from claim 29;

(22) a claim 42, worded similarly to original patent claim 20, but dependent from claim 29;

(23) a claim 43, reciting a signal primer comprising:

a) a target binding sequence which hybridizes to a target sequence at a position downstream of the position where a nucleic acid amplification primer hybridizes to the target sequence;

b) a 3' end which is extendable to generate a signal primer extension product, said signal primer extension product displaceable from the target sequence by extension of the nucleic acid amplification primer; and

c) a means for detecting the signal primer extension product;

(24) a claim 44, dependent from claim 43, reciting means for detecting the signal primer extension product selected from the group consisting of size which differs from that of a nucleic acid primer amplification product, chemical modification, special nucleotide sequence, and a structural feature;

(25) a claim 45, dependent from claim 44, reciting a chemical modification selected from the group consisting of an affinity ligand and a reporter group;

(26) a claim 46, dependent from claim 45, reciting an affinity label selected from the group consisting of avidin, streptavidin, biotin, haptens, antigens and antibodies;

(27) a claim 47, dependent from claim 45, reciting a reporter group selected from the group consisting of radioisotopes, fluorescent dyes, enzymes which react to produce detectable reaction products and visible dyes;

(28) a claim 48, dependent from claim 44, reciting a special nucleotide sequence selected from the group consisting of sequences which will form a triple helix by hybridization an oligonucleotide probe to a double stranded amplification product comprising a signal primer extension product hybridized to an amplification primer extension product and recognition sequences for double-stranded nucleic acid binding proteins;

(29) a claim 49, dependent from claim 44, reciting a structural feature comprising a nucleotide sequence which results in a double stranded restriction endonuclease recognition site in a secondary amplification product;

(30) a claim 50, reciting a nucleic acid amplification process comprising the signal primer of claim 43 hybridized to an extension product of a nucleic acid amplification primer.

The above noted additional reissue claims differ from the original patent claims and correct the errors in the original patent claims by not limiting the claims to only methods for concurrently generating a secondary amplification product and an amplification product, nor a particular embodiment of a SDA reaction.

These errors arose without any deceptive intent on the part of the applicants through an inadvertent oversight during the prosecution of the original patent application resulting in the original patent grant claiming less than we had a right to claim in the patent due to (a) the failure to appreciate the full scope of the invention, (b) the absence of claims 21 to 50, and (c) the limitation in all of the original patent claims to only methods, or a particular embodiment of a SDA reaction.

These errors were discovered after the issuance of U.S. Patent No. 5,547,861 upon examination of the patent and the art of record by patent counsel and upon a full appreciation of the scope of the invention and the prior art.

We assigned all right, title and interest in U.S. Patent No. 5,547,861 by assignment to Becton, Dickinson and Company of Franklin Lakes, New Jersey which was recorded in the U.S. Patent and Trademark Office.

We hereby offer to surrender the original patent grant for U.S. Patent No. 5,547,861.

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Power of Attorney

Petitioners hereby appoint:

Richard J. Rodrick	Registration No. 26,985
David W. Highet	Registration No. 30,265
John L. Voellmicke	Registration No. 30,348
Eric M. Lee	Registration No. 30,471
Allen W. Wark	Registration No. 30,503
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Susan A. Capello	Registration No. 34,560
Arthur D. Dawson	Registration No. 35,113
Jeremy Lack	Registration No. 35,813

as attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Correspondence and telephone calls are to be directed to:

David W. Highet
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417
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Date: May 1, 1998 By: James G Nadeau
James G. Nadeau

Date: May 1, 1998 By: George T. Walker
George T. Walker

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PTO/SB 91 (10-96)
Approved for [redacted] ugh 10/31/99. OMB 0651-0031
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(Also PTO Form 3.76)

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DESCRIPTION OF ARTICLES OR SERVICE TO BE FURNISHED

In re application of: James G. Nadeau et al.

Serial No.:

Filed: Herewith

For: DETECTION OF NUCLEIC ACID AMPLIFICATION

Assistant Commissioner for Patents
Washington, D.C. 20231
Sir:

Please provide a title report, as required for a reissue application according to 37 CFR 1.171, of the following U.S. patent:
U.S. Patent 5,547,861, issued to Becton Dickinson and Company on August 20, 1996 for DETECTION OF NUCLEIC ACID AMPLIFICATION.

The title report is to be placed in the file of the reissue application filed concurrently herewith.

If additional space is needed attach separate sheet.

(signature) David W. Highet

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PATENT
P-2821RI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	James G. Nadeau et al.		
REISSUE OF:	Patent No. 5,547,861	GROUP:	Not Assigned
FILING DATE:	Herewith	EXAMINER:	Not Assigned
FOR:	DETECTION OF NUCLEIC ACID AMPLIFICATION		

ASSENT OF ASSIGNEE UNDER C.F.R. §1.172(a)

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231

ON: May 20, 1998
(DATE OF DEPOSIT)

BY: Mary Lou Kittren
(NAME)

Mary Lou Kittren 5-20-98
(SIGNATURE) (DATE)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The undersigned declares that he is an officer of Becton, Dickinson and Company having a principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417 and organized under the laws of the State of New Jersey and that he is authorized to make this declaration on behalf of Becton, Dickinson and Company.

The entire right, title and interest of U.S. Patent No. 5,547,861 is vested in Becton Dickinson and Company by assignment recorded in the U.S. Patent and Trademark Office.

He believes the original patent grant U.S. Patent No. 5,547,861 is partially inoperative, through error without any deceptive intent by reason of Applicants claiming less than they had a right to claim in that Applicants mistakenly limited all claims to specify only methods or a particular embodiment of a Strand Displacement Amplification (SDA) reaction.

Becton Dickinson and Company hereby assents to the reissue application of U.S. Patent No. 5,547,861.

He further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and

the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

BECTON DICKINSON AND COMPANY

Date: May 14, 1990

By: Richard J. Kodrick
Name:

Title: Assistant Secretary

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